K093535

510(k) Summary

Date Prepared: November 13, 2009

MAR 2 2 2010

Submitter: Medtronic Perfusion Systems
7611 Northland Drive
Minneapolis, MN 55428
Establish Registration Number: 2184009

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Device Name and Classification:

Trade Name:	autoLog® Autotransfusion System
Common Name:	Autotransfusion Apparatus
Regulation Number:	21 CFR 868.5830
Product Code:	CAC
Classification:	Class II

Predicate Devices

autoLog® Autotransfusion System (K982755)

Device Description

The autoLog® Autotransfusion System is an autotransfusion apparatus (including disposable kit). The system is a centrifugal unit that is used to collect autologous blood peri-operatively and post-operatively into a collection reservoir with an appropriate amount of anticoagulant. This autologous blood is then processed by centrifugation, separating the red cells from the plasma. Contaminating debris is subsequently washed out by the introduction of normal saline in a wash cycle. The resulting packed red cells, suspended in normal saline, are pumped to a transfer bag, and may be reinfused to the patient.

Indications for Use

The autoLog is intended for use in the collection, concentration, washing, and reinfusion of autologous blood. Such areas of application may include, but are not necessarily limited to, the following:

- General, Cardiovascular, Orthopedic, Vascular, Plastic/Reconstructive, Obstetric/Gynecologic and Neurosurgical
- Postoperative treatment areas

Comparison to Predicate Devices

A comparison of the modified product and the currently marketed autoLog® Autotransfusion System indicates the following similarities to the system which received 510(k) clearance:

- Same indicated use
- Same operating principle
- Same disposables (wash kit)
- Same shelf life for disposables
- Same fluid path (patient-contacting) materials, while the manifold material is changing from PVC to PETG, the PETG material is already in use in the disposable bowl
- Patient-contacting devices are packaged and sterilized using identical materials and processes

Intended Use

There is no change to the intended use of the device.

Labeling

The Instructions for Use modifications include an itemized list of recovered and removed materials.

Summary of Performance Data

Biocompatibility and software validation test data were used to establish the performance characteristics of the modifications to this device. Clinical testing was not required to establish substantial equivalence. The following performance tests were conducted:

- Biocompatibility Testing
- Software Testing
- Manifold Bond Integrity Testing
- Fan Guard Cooling Testing
- Lipid Removal Characterization Testing

Conclusion

The modifications to the autoLog® Autotransfusion System described in this submission result in a substantially equivalent device because the fundamental scientific principle, labeling and the intended use are unchanged as a result of these device modifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MAR 2 2 2010

Medtronic Inc.
c/o Ms. Caralee Walton
Senior Regulatory Affairs Specialist
8200 Coral Sea Street NE
Mounds View, MN 55112

Re: K093535
autoLog® Autotransfusion System
Regulation Number: 21 CFR 868.5830
Regulation Name: Autotransfusion Apparatus
Regulatory Class: Class II
Product Code: CAC
Dated: January 25, 2010
Received: January 26, 2010

Dear Ms. Walton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Donna R. Lachman

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K093535

Device Name: autoLog® Autotransfusion System

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vedrnes

(Division Sign-Off)
Division of Cardiovascular Devices

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